MEDWATCH

Individual Safety Report

3169256-X-00-01

For use by user-facilities, butors and manufacturers for MANDATORY reporting

Teva Pharmaceuticals USA

Form Approved by FDA on 2/23/95

Mfr. report # 6065 - AR

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient Identifier: In confidence [redacted]

2. Age at time of event: Unknown

Date of birth: Unknown

3. Sex: ☒ female ☐ male

4. Weight: lbs or kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

☒ death 1/16/94 (mo/day/yr)

☐ life-threatening

☐ hospitalization-initial or prolonged

☐ disability

☐ congenital anomaly

☐ required intervention to prevent permanent impairment/damage

☐ other:

3. Date of event (mo/day/yr): 1/16/94

4. Date of this report (mo/day/yr): 9-Dec-1998

5. Describe event or problem

The attorneys representing the Estate of [redacted] stated that the deceased died on January 16, 1994 as a result of taking ordinary doses of [redacted] brand Extra-Strength Acetaminophen in combination with her regular consumption of alcohol.

Additional information 16-Sep-1998:
Follow-up information received in a summons from the attorney listed below indicated the patient had liver injury.

6. Relevant tests/laboratory data including dates

Not provided

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Alcohol use.

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Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Acetaminophen Caplets, 500 mg

#2 Alcohol

2. Dose, frequency & route used

#1 Unknown

#2 Unknown

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 Unknown

#2 Unknown

4. Diagnosis for use (indication)

#1 Unknown

#2 Unknown

5. Event abated after use stopped or dose reduced

#1 ☐ yes ☐ no ☐ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)

#1 2300

#2 N/A

7. Exp. date (if known)

#1 ??-Jan-1996

#2 N/A

8. Event reappeared after reintroduction

#1 ☐ yes ☐ no ☐ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

G. All manufacturers

1. Contact office-name/address (& mfrg site for devices)

TEVA Pharmaceuticals USA
1510 Delp Drive
Kulpsville, PA 19443

2. Phone number: (215) 256-8400

3. Report source (check all that apply)

☐ foreign
☐ study
☐ literature
☒ consumer
☐ health professional
☐ user facility
☐ company rep[illegible]tative
☐ distributor
☒ other: Attorney

4. Date received by manufacturer (mo/day/yr): 16-Sep-1998

5. (A)NDA #
IND #
PLA #
pre-1938 ☐ yes
OTC product ☒ yes

6. If IND, protocol #

7. Type of report (check all that apply)

☐ 5-day ☒ 15-day
☐ 10-day ☐ periodic
☐ initial ☒ follow-up # 1

8. Adverse Event term(s)

Death
Liver Damage

9. Mfr. report number: 6065-AR

E. Initial reporter

1. Name, address & phone #

[redacted], Esquire

[redacted]

DEC [illegible] 1998

2. Health professional? ☐ yes ☒ no

3. Occupation: Attorney

4. Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unk

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Continuation

Continuation for

C. Suspect Medications (continued):

1. [redacted] Sinus Tablets
2. **Dose, frequency, and route used:** Unknown
3. **Therapy dates:** Unknown
4. **Diagnosis for use:** Unknown
5. **Lot #:** P12604 **Expiration date:** ??-Aug-1996